

REMARKS

Claims 1-20 are all the claims pending in the application. Claims 21-24 have been cancelled. Applicants reserve the right to present the cancelled claims in another application.

As an initial matter, Applicants gratefully acknowledge the courtesy extended by the Examiner to the undersigned as well as Dr. Richard Handley, during the interview conducted March 31, 2004. A separate paper will be filed containing the substance of the interview. Additionally, the indication that Claims 11-20 are allowable (see, page 5 of the Office Action) is appreciated. For the reasons discussed below, however, it is believed that all of the claims are in condition for allowance.

The rejection of Claims 1-9 under 35 U.S.C. § 112, second paragraph, has been maintained “for the reasons of record.” It is also indicated that “the rejection is applicable to new claims 21-23.”

In particular, it is asserted in the Office Action that “a full description of the chemical features of the substituent groups essential for the intended use to occur is not found in the specification [and] a mere recitation of the examples without fully defining the substituents fails to provide the metes and bounds required of the instant claims.”

Applicants again respectfully traverse this rejection for the reasons set forth in the Amendment Under 37 C.F.R. § 1.111 filed July 23, 2003, and for the following additional reasons.

First, as mentioned above, it is indicated in the Office Action that this rejection is being maintained for the reasons of record. Accordingly, it is presumed that the Examiner's position in the most recent Office Action is that all of the criticisms of Claims 1-9 set forth in the Office Action dated January 24, 2003, have been maintained but with the exception of the criticism of the term "ring". This is because, in the Amendment Under 37 C.F.R. § 1.111 filed July 23, 2003, Claim 1 was amended to delete the proviso that allowed R¹ and R² to form a ring. This feature of the invention has been presented in a copending application.

Referring to pages 2 and 3 of the Office Action dated January 24, 2003, in Claim 1, the definitions of R¹ and R² are criticized on the basis that there is no clear definition of the substituents. Also, the definition of R⁴-R¹¹ is criticized on the basis that it "includes numerous classes of chemical compounds with diverse structures, including those not yet identified."

In Claim 1, R¹ and R² are defined as follows: "R¹ and R² are independently selected from alkyl, substituted alkyl, aryl, substituted aryl, aralkyl and substituted aralkyl of 1 to 20 carbon atoms."

As would be readily apparent to one of ordinary skill in the art, any suitable substituent may be utilized in R¹ and R². In this regard, suitable substituents are identified in the specification. In fact, a definition of the term "substituted" is provided at page 13, lines 6-10. ("Substituted – Refers to the replacement of at least one hydrogen atom on a group by a non-hydrogen group. It should be noted that in references to substituted groups it is intended that multiple points of substitution can be present unless clearly indicated otherwise.")

Further, referring to page 13, there is a description of the types of substituents that are suitable for use in the present claimed compounds by function, as well as a description of particular substituents. Namely, it is indicated that substituent groups other than hydrogen atoms, such as ionic groups or polar groups, can be incorporated in various numbers and at selected positions on the carbon chain or ring in order to modify the properties of the compound or to provide for convenience of synthesis. The properties are, for example, chemiluminescence quantum yield, rate of reaction with the enzyme, maximum intensity of light emission, duration of light emission, wavelength of light emission, and solubility in the reaction medium. Preferred groups conferring water solubility are identified as including sulfonate salt groups --SO_3^- , sulfate salt groups --OSO_3^- , phosphonate salt groups --PO_3^- , phosphate salt groups --OPO_3^{-2} , carboxylate salt groups --COO^- , and ammonium salt groups --NH_3^+ , and phosphonium salt groups --PR_3^+ . It is further described that one or more groups which permit covalent coupling to another molecule such as a specific binding partner can also be included as substituents on R^1 and R^2 . Exemplary specific substituents are identified as including, without limitation, alkoxy, aryloxy, hydroxy, halogen, amino, substituted amino, carboxyl, carboalkoxy, carboximide, cyano and sulfonate groups.

In addition, and as discussed in MPEP § 2173.04, breadth of a claim is not equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the term to be of a scope different from that defined in the claims, then the claims comply with the requirements of 35 U.S.C. § 112, second paragraph.

In the instant claims, the scope of the subject matter embraced by the claims is clear – any suitable substituent may be utilized in R¹ and R². Further, Applicants have not otherwise indicated that they intend the term “substituted” to be of a scope different from that defined in the claims. To the contrary, the specification describes the type of substituents that are suitable for use in the present claimed invention and gives examples that would be understood by one skilled in the art.

The definitions of R⁴-R¹¹ are also criticized. The Examiner queries in the Office Action dated January 24, 2003, what is “a substituent which can contain 1 to 50 atoms selected from C, H, N, O, S, P, Si, and halogen.” It is further indicated in that Office Action; “[s]uch a description includes numerous classes of chemical compounds with diverse structures, including those not yet identified.”

One of the functions of claims is to cover later developed improvements. Thus, the language criticized by the Examiner is intended to cover various chemical compounds with diverse structures, including those not yet identified. It is respectfully submitted that it is improper to object to the breadth of the claims in the context of an indefiniteness rejection under Section 112, second paragraph. See, above. The salient inquiry here is whether the scope of the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the term to be of a scope different from that defined in the claims. If so, then the claims comply with the requirements of 35 U.S.C. § 112, second paragraph.

The definition of R⁴-R¹¹ is clear. It is a group containing up to 50 atoms, the atoms being either carbon, hydrogen, nitrogen, oxygen, sulfur, phosphorous, silicon or halogen atoms.

Further, Applicants have given no indication that they intend the term “substituent” to be of a scope different from that defined in the claims. The specification is wholly consistent with the definition of $R^4\text{-}R^{11}$ recited in the claims. Referring to the paragraph bridging pages 14 and 15 of the specification, it is indicated that the groups R^4 to R^{11} each are a substituent that can contain 1 to 50 atoms selected from the same group as recited in Claim 1. These substituents permit the light to be produced and can include, for example, alkyl, substituted alkyl, aryl, substituted aryl, aralkyl, alkenyl, alkynyl, alkoxy, aryloxy, halogen, amino, substituted amino groups, carboxyl, carboalkoxyl, carboximide, cyano, sulfonate and phosphate groups. It is further indicated that preferably, R^4 to R^{11} are either, hydrogen, halogen, alkoxy groups, amino, or amino substituted with one or more alkyl or aryl groups. Still further, one of R^5 , R^6 , R^{10} or R^{12} is a chlorine atom and the remainder of $R^4\text{-}R^{11}$ are hydrogen atoms.

The specification further describes that pairs of adjacent groups, i.e., R^4 and R^5 , or R^5 and R^6 , or R^6 and R^7 , or R^8 and R^9 , or R^9 and R^{10} , or R^{10} and R^{11} , can join together as a carbocyclic or heterocyclic ring system comprising at least one 5- or 6-membered ring which is fused to the ring bearing the exocyclic double bond, such as an additional fused benzene ring making the resulting compound a benzacridan derivative.

Thus, Applicants respectfully submit that Claims 1-9 comply with the requirements of Section 112, second paragraph, and withdrawal of this rejection is requested.

Claim 1-9 have also been rejected under 35 U.S.C. § 112, first paragraph, on both lack of enablement and violation of written description grounds.

Applicants also respectfully traverse both of these rejections for the following reasons.

With regard to the asserted lack of enablement, it is indicated in the Office Action that “since the instant claims encompass numerous classes of structurally diverse compounds, some of ... whose structures are not fully described (see [the rejection based upon violation of the description requirement below]), and some are structurally unrelated to the example compounds, starting materials and the processes of making these compounds are not seen but required.” It is further indicated that “sources are particularly pertinent especially where the structures of these compounds are not fully defined.”

However, in order to make a rejection for lack of enablement, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. As the CCPA, the predecessor to the Federal Circuit has held, “it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

It is respectfully submitted that in rejecting Claims 1-9 under 35 U.S.C. § 112, first paragraph, for lack of enablement, the Examiner has not carried her burden to explain *why* she doubts that one skilled in the art would be able to make and use the instant claimed invention, and to back up her assertions with acceptable evidence or reasoning.

In this regard, as mentioned above, in the most recent Office Action, the Examiner has taken the position that “starting materials and processes of making these compounds are not seen but required.” However, the Examiner has made no effort to explain *why*, in the context of the present claimed invention and the specification of the instant Application, she doubts that suitable starting materials would be readily known and available to one of skill in the art. Instead, the Examiner has only made a blanket statement to the effect that since the claimed compounds cover “numerous classes of structurally diverse compounds,” the starting materials must not be known for all of the claimed compounds. However, the Examiner’s position is mere speculation. It sets forth no rationale for its conclusion and, in fact, is a non-sequitur. It does not necessarily follow that because Applicants broadly cover the compounds of the present invention in the claims, all of the starting materials and processes for making those starting materials must necessarily not be known and readily available to one skilled in the art. Accordingly, on this basis alone, the rejection should be withdrawn.

Further, without admitting that the Examiner has carried her burden, Applicants submit that the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied by Applicants’ specification because it discloses methods of making and using the claimed invention that bear

more than a reasonable correlation to the entire scope of the claimed invention, all that is required under the case law. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

First, it is well settled that the specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public.

In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Thus, in the instant Application, the specification is drafted at the level of one who is skilled in the art of chemiluminescence, and need not disclose starting materials and processes of making the starting materials that are well known to one skilled in that art.

In any event, the specification contains a detailed description of starting materials processes of using those starting materials that would enable one skilled in the art to make and use the present claimed invention. Referring to pages 19-22 of the specification, methods for manufacturing the compounds of the claimed invention are described including references to literature describing those methods.

For example, as described on pages 19-20 of the specification, methods for preparing compounds of formula I include nucleophilic addition of a lithiosilane compound or a phosphorous ylide to a suitable carbonyl compound according to the two reaction schemes described in Carey, et al., J. Org. Chem., 37, 1926-29 (1972) (and shown on page 20). Alternatively, an ester may be converted to a ketene-dithioacetal by reaction with a bis(dialkylaluminum) – dithiol reagent as described in Corey et al., Tetrahedron Lett., 925-8 (1975) (and as also shown on page 20 of the instant specification).

Yet another method utilizes an anion of an active methylene group reacted with CS₂ and the dithiocarboxylate is reacted with a reagent R¹-LG containing the R¹ group to form a dithioester. This technology is described in Shahak, et al., Tetrahedron Lett., 4207-10 (1973). The dithioester is converted into the enolate and reacted with a reagent of the formula R²-LG. Typical leaving agents include halogens, such as chloride, bromide and iodide, sulfonates such as methanesulfonate and p-toluenesulfonate and trifluoromethanesulfate, carboxylates such as acetate and benzoate particularly when X is an acyl group in which case the X-LG would be an acid anhydride, sulfates such as methosulfate, and other groups such as imidazole, triazole and tetrazole, maleimide, and succinimidoxyl groups. See, pages 20-21 of the specification.

In addition, in the examples beginning at page 33 of the specification, there is described detailed procedures including starting material, for making the claimed compounds. There is a description of the preparation of 39 compounds within the scope of the present claimed invention including references to starting materials. For the sake of brevity, these examples are not discussed in detail here. The Examiner's attention is directed to pages 33-50 of the specification.

In view of the foregoing, Applicants respectfully submit that the present claimed invention is clearly enabled by the specification. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is requested.

As mentioned above, Claims 1-9 have also been rejected under 35 U.S.C. § 112, first paragraph, for violation of the description requirement.

In this rejection, it is indicated that "although examples are given, a full written description for the substituents of the substituted alkyl, aryl, aralkyl and a full description for the

substituent containing 1-50 atoms selected from C, H, N, O, S, P, Si and halogen atoms are not found in the specification.” It is further indicated that “since a compound is defined by its structure formed by specific number and type of atoms in a specific bonding relationship, the mere recitation of atoms or function in the instant fails to provide a full description of the compound.”

Applicants also respectfully traverse this rejection for the following reasons.

The first paragraph of 35 U.S.C. § 112 requires that the "specification shall contain a written description of the invention . . ." This requirement is separate and distinct from the enablement requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

To satisfy the written description requirement, a patent specification must describe the claimed invention in such a way that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. An applicant shows possession of a claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner again has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See *Wertheim*, 541 F.2d at 263, 191 USPQ at 97 ("[T]he PTO

has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

It is respectfully submitted that the Examiner has misapplied the law, and is confusing the enablement and description requirements of the first paragraph of Section 112, first paragraph. This is because, in the present Application, the terms criticized by the Examiner as being the basis for the violation of the description requirement are clearly described in the specification in such a way that would convey to one skilled in the art that Applicants had possession of the claimed invention. In fact, all of the language criticized by the Examiner as violating the description requirement was part of the original claims. As discussed in MPEP §2163, when the objected to language is present in the original claims, there is a strong presumption that an adequate written description of the claimed invention is present. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

The original language of Claim 1 recited the definition of R¹ and R² as being independently selected from alkyl, substituted alkyl, aryl, substituted aryl, aralkyl and substituted aralkyl. In addition, the original language of Claim recited the definition of R⁴ to R¹¹ as being independently a substituent which can contain from 1 to 50 atoms selected from the Markush group recited in Claim 1. Thus, the specification, which includes the original claims, clearly describes the claimed invention.

In view of the foregoing, it is respectfully submitted that the present specification complies with the description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of this rejection is requested.

In summary, with respect to the rejections under 35 U.S.C. § 112, first and second paragraphs, Applicants submit that the Examiner has demonstrated a fundamental misunderstanding of the relevant legal concepts and as a result misapplied the law. Claim language is not indefinite under Section 112, second paragraph, because it is broad. Further, the enablement and description requirements of Section 112, first paragraph, are separate requirements. The enablement requirement is a requirement that the specification enable one skilled in the art to make and use the invention after the expiration of the patent. For the reasons discussed herein, the instant specification clearly meets this standard. In contrast, the description requirement is designed to ensure that the applicant had possession of that which he claims as his invention. The language criticized by the Examiner was part of the original claims. Thus, it is clearly described as being part of Applicants' invention.

Claims 1-4 have also again been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,126,870 to Akhavan-Tafti.

It is indicated that this rejection is "maintained for the reasons of record" and "the rejection is applicable to claims 10, 21-24." However, during the above-mentioned interview, the Examiner indicated that Claims 10 and 21-24 are not rejected over prior art.

Akhavan-Tafti is relied upon to "generically disclose a chemiluminescent acridine compound of formula I." It is indicated that "the acridan compound 20 differs from the second

compound of the first row in instant claim 10 in having an O instead of the instant S on the ketene carbon.” However, Akhavan-Tafti is further relied upon to teach that “O and S are optional choices.” The Examiner concludes that “at the time of the invention, one of ordinary skill in the art would be motivated to replace the O of the prior art example compound with the alternative S as taught by Akhavan-Tafti to arrive at the instant invention with the reasonable expectation of obtaining an additional chemiluminescence compound.”

With regard to Applicants reliance in the Amendment filed July 23, 2003, on the data in the specification, it is indicated that “only general statements are made in the cited pages without showing a side-by-side comparison between the closest prior art compound and the instant compound.” Thus, the Examiner concludes that “unexpected results therefore have not been established and the instant [claims remain] obvious over Akhavan-Tafti.”

Applicants again respectfully traverse this rejection.

Applicants respectfully submit that the presently claimed compounds are unexpectedly and dramatically superior to the compounds of the '870 patent. In this regard, reaction of a peroxidase with peroxide and the presently claimed compounds containing two sulfur atoms substituted at one end of the double bond exhibit dramatically enhances speed of generating chemiluminescence, reaching maximum intensity in one minute or less. Additional advantages of the present group of compounds are listed at page 19 of the specification, lines 17-27.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

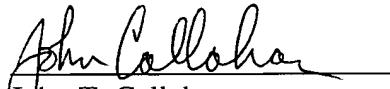
AKHAVAN-TAFTI et al.
Appln. No. 10/029,222
Amendment Under 37 C.F.R. § 1.111

Lum. 4.1-77

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: April 16, 2004

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Lum. 4.1-77

AKHAVAN-TAFTI et al.

Appln. No.: 10/029,222

Group Art Unit: 1625

Confirmation No.: 3442

Examiner: Evelyn Mei HUANG

Filed: December 10, 2001

For: IMPROVED COMPOUNDS FOR GENERATING CHEMILUMINESCENCE WITH A
PEROXIDASE

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on

Wednesday, March 31, 2004:

REMARKS

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: none
2. Identification of claims discussed: all
3. Identification of art discussed: U.S. Patent No. 6,126,870 to Akhanvan-Tafti
4. Identification of principal proposed amendments: none
5. Brief Identification of principal arguments: the claims comply with the requirements of 35 U.S.C. § 112, first and second paragraphs, and are not obvious from the '870 Patent.
6. Indication of other pertinent matters discussed: none

AKHAVAN-TAFTI et al.
Appln No. 10/029,222
Statement of Substance of Interview

Lum. 4.1-77

7. Results of Interview: no agreement reached but it was classified that Claim 10 is not rejected over prior art.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,


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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: April 16, 2004